

NOV - 6 2000

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510(k) Summary

Name of Sponsor: DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988
Est. Reg. No. 1818910

510(k) Contact: Marcia J. Arentz
Senior Regulatory Associate
Phone: (219) 371-4944
FAX: (219) 371-4940

Trade Name: Pe.R.I. II Knee Fracture System

Common Name: Bone fixation device

Classification: Class II Device per 21 CFR 888.3030:
Single/Multiple component metallic bone
fixation appliances and accessories

Device Product Code: Code: 87HRS
No performance standards have been established
under Section 514 of the Federal Food, Drug,
and Cosmetic Act for bone plates.

Substantially Equivalent Device: Synthes Proximal Tibia Plating System
Synthes Anatomical Locking Plate System (ALPS)
DePuy ACE Brooker Bone Plating System
DePuy ACE Supracondylar Plate

Device Descriptions: The Pe.R.I. II Knee Fracture System is a
contoured multi-hole fracture plate and fasteners
intended to be implanted either percutaneously or
by a traditional open method.

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510(k) Summary (continued)

Indications for use:

The Pe.R.I. II Knee Fracture System is intended for use in fracture fixation cases requiring Open Reduction Internal Fixation (ORIF) for closed and open fractures of the distal femur and proximal tibia including repair of non-unions, malunions and fractures including but not limited to simple comminuted, lateral wedge, depression, medial wedge, bicondylar, combinations of lateral wedge and depression and fractures with associated shaft fractures.

Substantial equivalence:

The Pe.R.I. II knee fracture system has the same intended use and basic design as the predicate devices and is therefore substantially equivalent.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Marcia J. Arentz
Senior Regulatory Associate
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
P.O. Box 988
Warsaw, Indiana 46581-0988

Re: K003235
Trade Name: Pe.R.I II Knee Fracture System
Regulatory Class: II
Product Code: HRS
Dated: October 16, 2000
Received: October 17, 2000

Dear Ms. Arentz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

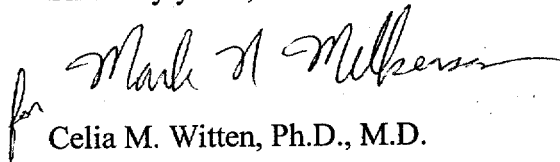
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

for Mark A. Milbrink

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and
Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): 00 3235

Device Name: **Pe.R.I. II Knee Fracture system**

Indications for Use:

The Pe.R.I. II Knee Fracture System is intended for use in fracture fixation cases requiring Open Reduction Internal Fixation (ORIF) for closed and open fractures of the distal femur and proximal tibia including repair of non-unions, malunions and fractures including but not limited to simple comminuted, lateral wedge, depression, medial wedge, bicondylar, combinations of lateral wedge and depression and fractures with associated shaft fractures.

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ☒ OR Over-The-Counter Use
(Per 21 CFR 801.109)

for Mark N. Melkers
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003235

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